DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 14, 2015

Ningbo HLS Medical Products Co., Ltd
% Leon Lu
Director of Quality and Regulatory Affairs
MEDevice Services, LLC
3500 South Dupont Highway
Dover, DE 19901

Re: K141057
Trade/Device Name: Disposable Cervical Brush
Regulation Number: 21 CFR 884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: HHT
Dated: March 18, 2015
Received: April 13, 2015

Dear Leon Lu,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141057

Device Name

Disposable Cervical Brush

Indications for Use *(Describe)*

The Disposable Cervical Brush is intended for the collection of cervical cells for analysis by Pap smear methods.

It is not intended for use in pregnant women and should be used by a clinician or other qualified health professional only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Date of Preparation: 05/13/2015

510(k) Owner:

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Device Information:

Trade name: Disposable Cervical Brush
Classification name: Obstetric-Gynecologic Specialized Manual Instrument (21 CFR 884.4530)
Regulation class: II
Product Code: HHT (Spatula, Cervical, Cytological)

Predicate Device:

Wallach CC/Brush (K896065)

Device Description:

The Disposable Cervical Brush is a non-sterile, disposable, colored cytological cervical spatula intended for collecting cytological materials from the surface of the cervix. This device consists of two components: a white colored head and a pink colored handle. The head contains a brush and a connection portion. The head and handle are physically connected through a male/female connection mechanism. The handle is made of Polypropylene (PP) and the head is made of low density polyethylene (LDPE). This device has a 3-years shelf-life.

Indications for Use:

The Disposable Cervical Brush is intended for the collection of cervical cells for analysis by Pap smear methods.

It is not intended for use in pregnant women and should be used by a clinician or other qualified health professional only.

Non-Clinical Tests Performed:

The following biocompatibility testing was conducted on this device to ensure safety:

- Cytotoxicity
- Vaginal irritation
- Guinea Pig Maximization Sensitization

The following mechanical testing was conducted on this device to ensure performance:

- Brush off test
- Joint strength (firm connection) test
- Bending strength resistance test
- Tensile strength at the bristle joint test
- Tensile strength at connection portion of the brush head test

The following chemistry testing was conducted on this device to ensure safety:

- Reduction material test
- Heavy metals test
- Cadmium test
- pH value test
- Dissolution tests of brush head and brush handle

Predicate Device Comparison:

Category	Subject (K141057)	Predicate (K896065)
Device	Disposable Cervical Brush	Wallach CC/Brush
Intended use	Same as the predicate	To collect the cervical cell specimen
Structure	Same as the predicate	The device consists of a brush head and a handle. The two parts are joined through the connection portion of the head.
Dimensions	Length overall – 208 mm Length of head – 30 mm Width of brush head – 21 mm	Length overall – 205 mm Length of head – 28 mm Width of brush head – 19 mm
Materials	Same as the predicate	Head – Low density polyethylene (LDPE) Handle – Polypropylene (PP)
Color	Same as the predicate	Colored

The subject and predicate devices have the same intended use and technological characteristics (design and materials). They also have comparable dimensions. The minor differences in dimensions do not raise any concerns. Thus, the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.